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10/802,395	03/17/2004	Marc S. Kreidler	MVMDINC.001CP4	3652

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KNOBBE, MARTENS, OLSON & BEAR, LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER
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STEELE, JENNIFER A

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/802,395	<b>Applicant(s)</b> KREIDLER ET AL.	
	<b>Examiner</b> JENNIFER STEELE	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 42-53, 62, 64-67, 69-73 and 75-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41, 54-61, 63, 68 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. **Claim 1-4, 20, 23-39, 54-61, 63 and 74 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366).**

Eldridge teaches a prothetic repair fabric comprised of a sheet of tissue infiltratable fabric and a second sheet of tissue infiltratable fabric which is fused to an adhesion resistant barrier forming a laminate composite prosthesis without degrading the mechanical properties or tissue ingrowth capability of the first sheet (ABST). Eldridge teaches that prior art prosthetic repair materials have raised the concern that mesh may form postoperative adhesions with abdominal viscera and to alleviate these concerns it had been proposed to cover the MARLEX mesh with an adhesion resistant



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barrier such as a sheet of ePTFE (col. 1, lines 16-27). Eldridge teaches the tissue infiltratable fabric is a mesh fabric such as a MARLEX mesh and the adhesion resistant barrier is layer of ePTFE (col. 1, lines 31-38 and col. 4, lines 6-21). Eldridge teaches a process for adhering the ePTFE barrier to the mesh wherein the mesh becomes encapsulated in the submicron porous network of the expanded PTFE sheet. The adhesion resistant barrier layer of ePTFE of Eldridge is equated with the porous first membrane layer. The MARLEX mesh of Eldridge is equated with the open mesh bonding layer. Eldridge differs from the current invention and does not teach a second porous membrane layer.

Shaw teaches a self expanding device for sealing a defect tissue or muscle (col. 1, lines 6-15). Shaw teaches a structure of thin membranes laminated together with an embedded super-elastic wire (col. 2, lines 37-47). Shaw teaches the membranes are of ePTFE cross-laminated to increase membrane strength. Shaw teaches the membranes are porous ePTFE (claim 65).

It would have been obvious to combine the features of the structure of Shaw that has multiple ePTFE membranes with a wire support with structure of Eldridge that teaches a support mesh with a single ePTFE membrane motivated to produce a biocompatible laminate for use in tissue repair that has the desired properties of porosity and resistance to tissue adhesion.

Regarding claim 2 and 37, Eldridge teaches a mesh support structure with only one membrane layer. Shaw teaches multiple membrane layers with an embedded wire support structure. It would have been obvious to combine the features of multiple



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membrane layers of Shaw with the mesh laminated membrane structure of Eldridge and the results of the combination would have been predictable. This is merely the duplication of parts which provide the same function.

With regards to claim 3, 4, 38 and 39, Eldridge teaches the laminate is porous and is intended for tissue growth and attachment and Eldridge teaches physical and performance characteristics were tested such as pore size, surface roughness, suture retention strength and burst strength (col. 5, lines 14-19). Eldridge teaches In-Vivo testing for tissue ingrowth (col. 6, lines 10-40).

As to claim 20, Eldridge teaches an average spacing between the mesh pores of 0.125 inches (col. 3, lines 47).

Regarding claim 23-25, Eldridge teaches a monofilament polypropylene which would have a melting point of 177°C (350°F). Eldridge teaches a process where the laminate is heated to a temperature of 350-400°F which is equal to 176 to 204°C. Applicant teaches a process where the laminate is heated to a temperature that is greater than the softening temperature of the bonding layer and less than the membranes and that temperature is in the range of 100 to 300 degree Celsius [0102]. The bonding layer softening point of Eldridge is equated with the bonding layer softening point of the current application.

As to claims 26, Eldridge teaches an ePTFE layer of thickness 0.0035 inches which is in the range of claim 26.

As to claim 27, Eldridge differs and does not teach an ePTFE membrane layer thickness of 0.001 to 0.002 inches. Shaw teaches ePTFE membranes that can have a



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thicknesses in the range of approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches and in the range of the membrane thicknesses that are claim 27.

Regarding claim 28 and 29, Eldridge differs and does not teach the property of open surface area of the membrane. Eldridge teaches the ePTFE membranes have a surface pore size of 0.74 +/- 0.3 microns (Table 1, col. 6). As Eldridge is teaches a membrane biocompatible laminate comprised of ePTFE which is the same materials and structure as the claimed invention, it is presumed that the property of surface area would be inherent to the structure of the claimed invention.

As to claims 30-35, Eldridge teaches the same membrane material as the Applicant, the property of softening point is presumed to be the same as the Applicants. Eldridge further teaches that the bonding layer or knit mesh melts and becomes encapsulated in the porous network of the PTFE sheet and therefore teaches that the bonding layer is of a lower melting temperature than the membrane.

Regarding claims 36-39, Eldridge laminate material is implantable and therefore, the above rejection of Eldridge in view of Shaw meets the new limitation of an implantable medical device comprising a biocompatible laminate.

As to claims 54-60, Eldridge in view of Shaw teaches a laminate membrane for use as a medical device comprising a first membrane a bonding mesh layer and a second membrane as noted above. Eldridge in view of Shaw differ from the current application and does not teach the property of open surface area in the range between about 10-50%. However as the laminate of Eldridge in view of Shaw teaches the



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structure and materials of the claimed invention, it is presumed that the property of open surface area would be inherent in this structure.

As to claim 55, Eldridge teaches an ePTFE membrane.

As to claim 56, Eldridge teaches a membrane of a thickness of 0.0035 inches.

As to claim 57, Eldridge teaches a pore size of 0.74 +/- 0.3 micron which could be 1.04 micron and therefore encompasses the claimed range about 1 micron to about 200 micron.

As to claim 58, Eldridge differs and does not disclose the internodal distance in the membrane. As Eldridge teaches the same materials and structure of the claimed invention, it is presumed that the property of internodal distance is inherent to the structure of the ePTFE membrane of Eldridge.

As to claim 59, Eldridge teaches a mesh bonding layer comprised of polypropylene and differs and does not teach a polyethylene mesh bonding layer. Shaw teaches membrane layers that can be manufactured of polyester, polyethylene, polypropylene, fluoropolymers, polyurethane foamed films, silicone, nylon, silk, thin sheets of super-elastic materials, woven materials or any other biocompatible materials (col. 4, lines 58-68). It would have been obvious to substitute polyethylene for polypropylene in the bonding layer mesh.

As to claim 60, Eldridge teaches a laminate of a thickness of 0.0635 inches which is in the range of claim 60.

Regarding claims 61, 63 and 74 that are drawn to a medical device comprising a frame wherein the frame is configured for use as a stent, Eldridge differs from the



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current application and does not teach a frame or a laminate for a stent. Shaw teaches a composite laminate that is configured with an elastic wire frame structure so that the device can be collapsed and then expanded. Shaw teaches a star shaped wire frame for a defect closure device as shown in Fig. 1 (col. 5, lines 28-40).

**2. Claim 5-19, 21, 22, and 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366) and in further view of Notaras et al (WO 9603091).**

As to claims 5-9, and 40-41, Eldridge teaches a laminate wherein the mesh fabric has a thickness of 0.06 inches and a membrane with a 0.0035 inch thickness and an overall thickness of 0.0635 inches. The thickness of Eldridge is greater than the claimed invention because the mesh is thicker than the claimed invention.

Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches. While Shaw laminates of 2,4,6, 8 and 10 plies, Shaw teaches a total laminate thickness between 0.0002 to 0.002 which overlaps the range of the claimed invention. Shaw presents a finding to one of ordinary skill in the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a reasonable expectation of success. As Shaw teaches the individual layer thicknesses of the ePTFE film in the range of 0.0002 to 0.002 inches and teaches that a range of plies can be employed, Shaw teaches a laminate that could be no more that 2 or 3 times the first or second membrane layer thicknesses.



Notaras teaches a surgical mesh of substantially uniform thickness that is useful for hernia repair and abdominal wall reinforcement (page 1, lines 1-5). Notaras teaches the mesh thickness is from 0.05 to 2 mm thick which is 0.0019 inches to 0.078 inches thick.

It would have been obvious to one of ordinary skill in the art to employ a membrane laminate with an overall thickness as taught by Shaw employing a structural mesh of thickness as taught by Notaras motivated to produce a thin laminate for tissue repair. As Shaw and Notaras teach that it is known in the art to produce a membrane laminate and mesh of thicknesses in the range of the claimed invention, one of ordinary skill in the art could have combined the elements with a reasonable expectation of success.

Regarding claims 14-17, Eldridge in view of Shaw differ and do not teach a mesh bonding layer with an average thickness of 0.0005 to 0.005 inches. Notaras teaches a surgical mesh with a thickness of 0.0019 to 0.078 inches which is in the claimed ranges of 0.0008 to 0.004 inches and 0.0009 to 0.003 inches and 0.001 to 0.002 inches. It would have been obvious to one of ordinary skill in the art to employ the mesh of Notaras motivated to produce a surgical laminate of the desired thickness.

With respect to claims 18-19, Eldridge teaches a mesh bonding layer that has a knit structure with a predetermined spacing pattern (col. 3, lines 42-50) but differs and does not teach the average pore cross-section. Notaras teaches a surgical mesh with a pore size that may be determined according to the use of the mesh for a particular operation. Notaras teaches it may be above 100 micron such as 0.5 to 10 mm,



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preferably 1.5 to 4 mm (page 4, lines 26-36). Notaras teaches a mesh that is 0.019 inches to 0.39 inches, preferably 0.06 inches to 0.16 inches. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a mesh with a pore size as taught by Notaras motivated to produce the desired properties of strength, porosity and adhesion in the laminate.

As to claims 21 and 22, Eldridge in view of Shaw and Notaras differ and do not teach the feature of open surface area of the bonding layer. Eldridge teaches the spacing between the pores can be 0.125 inches and in the range of the claimed invention. Notaras teaches a mesh with an average pore size in the range of the claimed invention and teaches the pore sized may be determined according to the use for the particular operation. However as Eldridge and Notaras teach the structure and materials of the claimed invention, it is presumed that the feature of open surface area would be inherent to the meshes of prior art and therefore it would have been obvious to employ a bonding mesh with an average open surface area of 10-90% and 30- 60% motivated to produce the desired properties of strength, porosity and adhesion.

### ***Response to Arguments***

3. Applicant's arguments, with respect to previous reference to Melican have been fully considered and are persuasive. The 35 USC 102(b) rejection of claims 1-4, 23-25, 36-39 has been withdrawn. The reference to Melican is not available as prior art as the filing date of this application claims priority to 09/435,562 that has a filing date of Nov. 8,



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1999. New grounds of rejection is presented in this Office Action and therefore the rejection is a Non-Final Action.

4. Applicant's arguments, with respect to previous reference to Melican have been fully considered and are persuasive. The 35 USC 103(a) rejection with respect to Melican in view of Shaw of claims 5-13, 26-27, 40-41 has been withdrawn.

5. Applicant's arguments, with respect to previous reference to Melican have been fully considered and are persuasive. The 35 USC 103(a) rejection with respect to Melican in view of Notaras of claims 14-19 has been withdrawn.

6. Applicant's arguments, with respect to previous reference to Melican have been fully considered and are persuasive. The 35 USC 103(a) rejection with respect to Melican in view of Clubb of claims 20-22 and 54 has been withdrawn.

7. Applicant's arguments, with respect to previous reference to Melican have been fully considered and are persuasive. The 35 USC 103(a) rejection with respect to Melican in view of Shaw and Hill of claims 28-35, 54-61, 63 and 68 has been withdrawn.

8. Applicant's arguments with respect to claim 1, 36, 54, 61 and 74 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./  
Examiner, Art Unit 1794

/D. Lawrence Tarazano/  
Supervisory Patent Examiner, Art  
Unit 1794

10/10/2008